



University of Northern Colorado

Institutional Animal Care and Use Committee

IACUC Policy 1.01 Modifications to Approved Protocols

This policy defines what constitutes a significant change to an approved protocol that requires IACUC approval of an amended protocol.

Regulatory Provisions: PHS Policy IV.C.1.
AWR §2.31(d)(1)
NIH Notice NOT-OD-03-045 (minor personnel changes)

The Animal Welfare Regulations and the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) require that the Institutional Animal Care and Use Committee review and approve significant changes regarding the use of animals as described in an IACUC approved Animal Use Protocol. Neither the USDA nor OLAW, however, provide a strict definition of “significant changes”.

The UNC IACUC chooses to follow the guidance provided by OLAW at: <http://grants.nih.gov/grants/olaw/faqs.htm>

1. SIGNIFICANT CHANGES

Examples of changes considered to be significant and requiring IACUC approval include, but are not limited to the following when the change is to be for the duration of the original protocol. Changes:

- a. alter the objectives of a study
- b. from non-survival to survival surgery
- c. resulting in greater pain and/or distress
- d. resulting in a greater degree of invasiveness
- e. in the species being used
- f. that increase the approximate number of animals being used by 10% or more
- g. in the principal investigator(s)
- h. in anesthetic agent(s) being used
- i. in the use or withholding of analgesics
- j. in the method of euthanasia
- k. in the duration, frequency, or number of procedures performed on an animal
- l. that add the use of hazardous materials or controlled substances

2. OTHER CHANGES

Proposed changes that do not fit one of the above categories may or may not be determined to be significant, such determination to be made by the Chair.

Changes in personnel other than the Principal Investigator(s) will not be considered significant; however, the addition of any person to an on-going protocol will require submission of a completed and signed Personnel Qualification Form.

Any changes not deemed significant will be reported to the IACUC by the Chair at its next regular meeting.

3. PROTOCOL AMENDMENTS

Any significant change as defined in number 1 above, or any other change that is determined by the IACUC Chair to be significant as described in number 2 above, must be approved by the IACUC prior to being implemented. Modifications will be approved for the duration of time remaining in the original approved protocol and will not begin a new three-year project period.

Written by/date:	Effective date:	Revision date:	Policy:
Arlene Hansen / 11/2007	11/27/07		IACUC 1.01